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Section 5: 510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Applicant: Bionova Medical, Inc.
8275 Tournament Drive Suite 160
Memphis, TN 38125
Ph: (901) 748-2581
Fax: (901) 748-2583

Official Correspondent: M Squared Associates, Inc
Deborah Lavoie Grayeski
901 King Street, Suite 200
Alexandria, VA 22314
Phone: 703-562-9800 ext. 250
Fax: 703-562-9797
Email: dgrayeski@msquaredassociates.com

Date of Submission: July 27, 2011

Proprietary Name: Sentrex BioSponge Wound Dressing

Common Name: Dressing, Wound, Drug

Regulatory Class: Unclassified

Product Codes: FRO

Predicate Device(s):

- K071552, Puracol Plus AG Collagen Microscaffold BioSponge
- K080010, NOCC Hydrophilic BioSponge
- K092552, Scion Cardiovascular Clo-Sur^{PLUS} P.A.D.

Device Description:

The Sentrex BioSponge Wound Dressing is a sterile, porous, soft chitosan sponge dressing that provides a moist healing environment to support wound healing. The Sentrex Wound Dressing is provided dry, in 10 cm x 10 cm and 5 cm x 5 cm squares. The dressing is made of chitosan, a naturally occurring, biocompatible polysaccharide derived from shellfish. The shells are processed and chemically treated. Once in bandage form, they are sterilized by gamma irradiation and packed in a heat-sealed foil laminate pouch. The Sentrex Wound Dressing may be moistened with saline in accordance with physician recommendation.

Intended Use:

The Sentrex BioSponge Wound Dressing is indicated in the dressing and management of:

- Full thickness and partial thickness wounds
- Pressure ulcers
- Venous ulcers
- Ulcers caused by mixed vascular etiologies
- Diabetic ulcers
- First and second degree burns
- Donor sites and other bleeding surface wounds
- Abrasions
- Trauma wounds healing by secondary intention
- Dehisced wounds
- Surgical wounds
- Dehisced surgical wounds

Summary of Technological Characteristics

The Sentrex BioSponge Wound Dressing is a sterile, porous, soft sponge dressing manufactured by a proprietary process from chitosan, a non-toxic, biodegradable, biocompatible, natural-based biopolymer. Chitosan has extensive safety data associated with its use in biomedical applications. Like collagen, chitosan induces a minimal foreign body reaction and retains more moisture than standard gauze, providing a moist environment to support wound healing.

Summary of Nonclinical Testing

Numerous studies including, biocompatibility testing, local tissue response testing, and bacterial inhibition (AATCC Test Method 100, Microbial Strike-Through Test, and Kirby-Bauer Antimicrobial Susceptibility Test performed with the naïve Sentrex BioSponge and the Sentrex BioSponge with antibiotics) testing demonstrate the performance of the Sentrex BioSponge Wound Dressing.

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Determination of Substantial Equivalence

The claim of substantial equivalence of the Sentrex Wound Dressing to the predicate devices is based on the comparison of the intended use, product technical/material characteristics, and performance characteristics. Bionova Medical, Inc. considers the Sentrex BioSponge Wound Dressing to be as safe and as effective, with substantially equivalent performance to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN - 5 2012

Bionova Medical Inc.
% M Squared Associates, Inc
Ms. Deborah Lavoie Grayeski
901 King Street Suite 200
Alexandria, Virginia 22314

Re: K112191
Trade/Device Name: Sentrex Biosponge Wound Dressing
Regulation Class: Unclassified
Product Code: FRO
Dated: May 29, 2012
Received: May 30, 2012

Dear Ms. Deborah Grayeski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D. Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Section 4: Indications for Use Statement

510(k) Number: K112191

Device Name: Sentrex BioSponge Wound Dressing

Indications for Use:

The Sentrex BioSponge Wound Dressing is indicated in the dressing and management of:

- Full thickness and partial thickness wounds
- Pressure ulcers
- Venous ulcers
- Ulcers caused by mixed vascular etiologies
- Diabetic ulcers
- First and second degree burns
- Donor sites and other bleeding surface wounds
- Abrasions
- Trauma wounds healing by secondary intention
- Dehisced wounds
- Surgical wounds
- Dehisced surgical wounds

Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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